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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/648,816	08/25/2000	Michael R. Yeaman	660081.415C1	6324

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MCDERMOTT, WILL & EMERY
4370 LA JOLLA VILLAGE DRIVE, SUITE 700
SAN DIEGO, CA 92122

EXAMINER

KAM, CHIH MIN

ART UNIT	PAPER NUMBER
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1653

DATE MAILED: 05/27/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<p align="center">Office Action Summary</p>	<p>Application No.</p> <p>09/648,816</p>	<p>Applicant(s)</p> <p>YEAMAN ET AL.</p>	
	<p>Examiner</p> <p>Chih-Min Kam</p>	<p>Art Unit</p> <p>1653</p>	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 March 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 67-79 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 67-79 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

1. The Request for Continued Examination (RCE) filed March 17, 2005 under 37 CFR 1.114 is acknowledged. An action on the RCE follows.

Status of the Claims

2. Claims 67-79 are pending.

Applicants' amendment filed on March 17, 2005 is acknowledged, and applicants' response has been fully considered. Claim 67 has been amended. Since claims 70-74 and 76-79 directed to amino acid sequences (SEQ ID NOs: 4-8 and 10-13) encompassed by claim 67, upon reconsideration, claims 70-74 and 76-79 will be included for examination. Therefore, claims 67-79 are examined.

Rejection Withdrawn

Claim Rejections - 35 USC § 112

3. The previous rejection of claims 67-69 and 75 under 35 U.S.C. 112, second paragraph, regarding the term "mimetics", is withdrawn in view of applicants' amendment of the claim, and applicants' response at pages 4-6 in the amendment filed March 17, 2005.

Claim Rejections - 35 USC § 102

4. The previous rejection of claims 69 and 75 under 35 U.S.C. 102(b) as being anticipated by Darveau *et al.* (U. S. Patent 5,409,898), is withdrawn in view of applicants' response at pages 6-7 in the amendment filed March 17, 2005.

Claim Rejections-Obviousness Type Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed.

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Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5. Claims 67-69, 76 and 79 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U. S. Patent 6,743,769. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 67-69, 76 and 79 in the instant application disclose an isolated antimicrobial peptide comprising a 7 amino acid core sequence: aa1-aa2-aa3-aa4-aa5-aa6-aa7, where amino acid residue at each position is defined, and synthetic analogs of the 7 amino acids that retain antimicrobial activity, wherein the antimicrobial peptide consists of an amino acid sequence having 13-74 amino acids; and an antimicrobial peptide comprising SEQ ID NO:3, 10 or 13. This is obvious variation in view of claim 1 of the patent which disclose an antimicrobial peptide comprising amino acid sequence of SEQ ID NO:3, 10, 13 or 14. Both sets of claims cite an antimicrobial peptide comprising amino acid sequence of SEQ ID NO:3, 10 or 13. Thus, claims 67-69, 76 and 79 in present application and claim 1 in the patent are obvious variations of an antimicrobial peptide comprising amino acid sequence of SEQ ID NO:3, 10 or 13.

6. Claims 67-69 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-2 of co-pending application 10/225,562 (based on the elected group I, claims 1-68). Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 67-69 in

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the instant application disclose an isolated antimicrobial peptide comprising a 7 amino acid core sequence: aa1-aa2-aa3-aa4-aa5-aa6-aa7, where amino acid residue at each position is defined, and synthetic analogs of the 7 amino acids that retain antimicrobial activity, wherein the antimicrobial peptide consists of an amino acid sequence having 13-74 amino acids; and an antimicrobial peptide comprising SEQ ID NO:3 (Ala-Leu-Tyr-Lys-Lys-Leu-Leu-Lys-Lys-Leu-Leu-Lys-Ser-Ala-Lys-Lys-Leu-Gly, 18 amino acids). This is obvious variation in view of claims 1-2 of the co-pending application which disclose a context-activated peptide comprising an amino acid sequence of SEQ ID NO:1, 2, 3 or 4, where the context-activated peptide, SEQ ID NO: 1 (33 residues), 2 (36 residues), or 4 (39 residues) contains the antimicrobial peptide of SEQ ID NO:3 (18 amino acids). Both sets of claims cite a peptide comprising the amino acid sequence of SEQ ID NO:3 (18 amino acids). Thus, claims 67-69 in present application and claims 1-2 in the co-pending application are obvious variations of a peptide comprising amino acid sequence of SEQ ID NO:3 (18 amino acids).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 67-79 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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Claims 67-79 are indefinite because of the use of the term “wherein said antimicrobial peptide consists of an amino acid sequence having 13-74 amino acids”. The term cited renders the claim indefinite, it is not clear whether the antimicrobial peptide consists of an amino acid sequence of 13-74 amino acids, or comprises an amino acid sequence of 13-74 amino acids, since the term cites “consist of” (a close language) and “having” (reads as “comprising”, an open language) at the same time. Claims 68-79 are included in the rejection because they are dependent on rejected claims and do not correct the deficiency of the claim from which they depend.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 67-68 are rejected under 35 U.S.C. 102(b) as anticipated by Darveau *et al.* (U. S. Patent 5,409,898, April 1995).

Darveau *et al.* disclose a cationic oligopeptide such as Ala-Leu-Tyr-Lys-Lys-Leu-Leu-Lys-Lys-Leu-Leu-Lys-Ser-Ala-Lys-Lys-Leu-Gly which has α helical amphiphilic structure and antibacterial activity (column 12, lines 31-32 and 49-54), this peptide contains the sequence of Ala-Leu-Tyr-Lys-Lys-Leu-Leu which is the synthetic analog of the 7 amino acid core sequence (Ala-Leu-Tyr-Lys-Lys-Phe-Lys) that retains antimicrobial activity (claims 67-68).

9. Claims 67 and 68 are rejected under 35 U.S.C. 102(b) as anticipated by Kupsch *et al.* (The EMBO Journal 12, 641-650, 1993).

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Kupsch *et al.* disclose one member of variable opacity (Opa) outer membrane proteins, OPA 65 has 236 amino acids and comprises a sequence of ARYRKWK, which is the same as the core sequence of the claimed invention (Fig. 4; see sequence match; claims 67 and 68). The OPA 65 protein would be expected to have antimicrobial activity because it contains the same core sequence as the claimed invention. The limitation “wherein said antimicrobial peptide consists of an amino acid sequence having 13-74 amino acids” reads as the antimicrobial peptide comprising 13-74 amino acids (see paragraph 7 above).

In response, applicants indicate claim 67 cites an isolated antimicrobial peptide having 13 to 74 amino acids, while Opa 65 has 236 amino acids (page 7 of the response). The response has been considered, however the argument is not found persuasive because claim 67 cites “the antimicrobial peptide consists of an amino acid sequence having (reads as comprising) 13 to 74 amino acids”, which indicates the claimed peptide can have more than 13 to 74 amino acids (see paragraph 7 above).

Conclusion

10. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (571) 272-0948. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner’s supervisor, Christopher Low can be reached on (571) 272-0951. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 308-4227 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Chih-Min Kam, Ph. D.
Patent Examiner



**CHIH-MIN KAM
PATENT EXAMINER**

May 26, 2005